Supreme Court, U.S.
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No. 91-1612

In The

Supreme Court of the United States

October Term, 1991

MARY KATHRYN THOMAS,

Petitioner,

vs.

HOFFMANN-LaROCHE, INC.,

Respondent.

Petition For Writ Of Certiorari To the United States Court Of Appeals For The Fifth Circuit

PETITION FOR WRIT OF CERTIORARI SUPPLEMENTAL APPENDIX

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APPENDIX C

Mary Kathryn THOMAS, Plaintiff,

v.

HOFFMAN-LA ROCHE, INC.,
Defendant.

Civ. A. No. EC 86-19-D-D.

United States District Court,
N.D. Mississippi, E.D.

Nov. 16, 1989.

* * *

H.J. Davidson, Jr., Carter & Davidson, Columbus, Miss., and John A. Owens and Susie Taylor Carver, Phelps, Owens, Jenkins, Gibson & Fowler, Tuscaloosa, Ala., for plaintiff.

Earl Keyes, Keyes, Dank, Moss & Leonard, Jackson, Miss., and John Winter, Patterson, Belknap, Webb & Tyler, New York City, for defendant.

MEMORANDUM OPINION

DAVIDSON, District Judge.

The court addresses the post-trial motion filed pursuant to Federal Rule of Civil Procedure 50(b) by the defendant Hoffman-La Roche, Inc. for judgment notwithstanding the verdict or in the alternative for a new trial. The case is a products liability action involving the pharmaceutical drug Accutane that is manufactured and distributed by the defendant. Judgment awarding $1 million in compensatory damages to the plaintiff was entered after a lengthy jury trial. In considering subject motion,

this court is bound by the precedent and pronouncements of the Fifth Circuit Court of Appeals as recently stated in a pharmaceutical products liability case, *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir.), *reh'g denied, modified* 884 F.2d 166, *reh'g en banc denied,* 884 F.2d 167 (1989), citing the seminal case of *Boeing Company v. Shipman*, 411 F.2d 365, 375-375 (5th Cir.1969). The foregoing cases counsel that if there is evidence of such quality and weight that reasonable and fair-minded jurors in the exercise of impartial judgment might reach different conclusions, then the motion for judgment notwithstanding the verdict should be denied. Further, that the court in considering subject motion is obligated and required to review the evidence in light of and with all reasonable inferences that are most favorable to the party opposed to the motion. Accordingly, this court in the case *sub judice* must examine all of the evidence and if upon such examination the court is convinced that the evidence, facts, and inferences point so overwhelmingly in favor of one party that reasonable jurors could not arrive at a contrary verdict then the motion for judgment notwithstanding the verdict should be granted. Further, in order to create a viable jury question there must be a conflict in substantial evidence, a mere scintilla of the evidence being insufficient to create a jury question. *Boeing, supra* pp. 374-375. After carefully reviewing the evidence in the case *sub judice,* the court is of the opinion that the motion for judgment notwithstanding the verdict is well taken and that the same should be granted. *See also Medtronic, Inc. v. Intermedics, Inc.*, 799 F.2d 734, 742 (Fed.Cir. 1986).

CAUSATION

In the case *sub judice*, the plaintiff's proof as to causation rested on the testimony of one of her treating physicians, Dr. Lawrence Mahalak, a neurologist from Jackson, Mississippi, and a neurologist from Houston, Texas, Dr. William J. Riley, who examined certain medical records relative to the plaintiff's hospital course and treatment. It should be noted that the physician who prescribed the drug accutane, Dr. Robert P. Myers of Columbus, Mississippi, had been treating the plaintiff for several years prior to prescribing the drug. He testified that the plaintiff suffered from recalcitrant cystic acne and had been nonresponsive to antibiotic treatment for a period of several years. Dr. Myers testified that on or about January 24, 1984 he prescribed the drug Accutane for the plaintiff. The plaintiff, a 54 year old female, took the drug during January and February 1984 until the onset of her neurological problems on or about February 24, 1984. She was initially hospitalized in St. Dominic's Hospital in Jackson, Mississippi on February 29, 1984 and demonstrated significant neurological problems at that time. On March 6, 1984 she was transferred to the Mayo Clinic in Rochester, Minnesota where she suffered a grand mal seizure. The initial hospitalization at Mayo Clinic was from March 6, 1984 through March 23, 1984. On May 16, 1984, the plaintiff was again hospitalized at St. Dominic's Hospital under the care of Dr. Mahalak, was again transferred to Mayo Clinic on May 22, 1984 where she was examined and treated and released on May 26, 1984. The plaintiff was hospitalized again with neurological problems on June 10, 1984 at the University of South Alabama Hospital in Mobile, Alabama for a period of five days. During

all of these periods of hospitalization, the plaintiff was disoriented, at times comatose, nonresponsive and generally evidenced serious neurological problems.[1] The plaintiff on each occasion was examined and treated by highly qualified specialists in the fields of neurology and infectious diseases. In proving her case as to causation, the plaintiff relied on the testimony of Dr. Lawrence Mahalak and Dr. William J. Riley.[2]

In addressing the current post-trial motions, the court has thoroughly examined the testimony of Dr. Mahalak and the deposition testimony of Dr. Riley. These physicians ultimately testified that in their opinion the ingestion by the plaintiff of the drug Accutane in January and February 1984 caused the seizures experienced by the plaintiff in 1984. In carefully reviewing the testimony of these doctors the court finds a total absence of any reference to epidemiological data or to any epidemiological study to support their opinions. Further, in closely examining the testimony of Dr. Mahalak who treated Mrs.

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[1] The plaintiff did not experience another seizure until the spring of 1989 when she suffered an episode similar to the 1984 occurrences.

[2] The plaintiff offered a Dr. James O'Donnell of Chicago, Illinois who held degrees in pharmacy and nutrition as an expert on causation. After lengthy *voir dire*, and applying Federal Rules of Evidence 702 and 703, this court held that O'Donnell would be permitted to express his opinion as to the adequacy of warnings furnished to the medical community by the defendant herein but did not permit O'Donnell to testify as to his opinion as to causation of the seizures suffered by the plaintiff. *See Viterbo v. Dow Chemical Co.*, 826 F.2d 420 (5th Cir.1987)

Thomas during her hospitalization at St. Dominic's hospital and further treated her as her regular physician after her second discharge from Mayo Clinic in May 1984, for many months agreed with the diagnosis of Dr. Swanson and the other physicians from the Mayo Clinic that Mrs. Thomas' problems were subacute encephalopathy with an etiology of uncertain origin although most compatible to some type of infectious etiology, most likely viral. It appears from the record that Dr. Mahalak initially diagnosed the plaintiff's problem as acute organic brain syndrome of undetermined etiology. It further appears from the record that Dr. Mahalak for many months and perhaps years did not dispute the diagnosis made by the several doctors at Mayo Clinic and the University of South Alabama and his own infectious disease consultant, Dr. Causey of Jackson, Mississippi. These doctors opined that the 1984 seizures experienced by the plaintiff were viral in origin, being a viral meningitis or encephalitis. Further, the infectious disease specialist and consultant, Dr. Causey, testified that viral encephalitises, in particular the herpes simplex, were likely origins of the plaintiff's neurological problems. Dr. Mahalak ultimately testified that in his opinion the drug Accutane was responsible for the plaintiff's 1984 seizures.

Dr. Mahalak testified at trial that his opinion was based on his observations of the plaintiff over a period of several years, his review of the medical records, and examination of certain adverse experience reports furnished to the Food and Drug Administration by Hoffman-La Roche and medical literature that he had read. At no time during his testimony did Dr. Mahalak refer to any epidemiological study or data. Further, it should be

noted that Dr. Mahalak was of the opinion that the seizure suffered by the plaintiff in the spring of 1989 was not in any way related to the drug Accutane and was a separate episode and process from the 1984 seizures.

In reaching his opinion that Accutane caused the 1984 seizures and neurological problems, it appears to the court that Dr. Mahalak relied primarily on his elimination of other causes of the plaintiff's 1984 seizures and related problems.[3] The doctor never testified that he relied on any specific data discussed in any medical literature or that he was knowledgeable of any chemical mechanism associated with the drug Accutane that would cause the seizures and related neurological problems experienced by the plaintiff. In this regard the court must note that the opinion expressed by Dr. Mahalak contrasts with the diagnosis of Dr. Swanson at the Mayo Clinic, of Dr. Chalhub of Mobile, Alabama. Dr. Kase and the infectious disease specialist, Dr. Causey, all of whom testified that in their opinion the seizures were viral in origin with the most prevalent diagnosis being an encephalitis caused by the herpes simplex or some other infection. Dr. Mahalak apparently came to the conclusion that Accutane was related to Mrs. Thomas' 1984 seizures at some point in time near the taking of his deposition by the defendants in the case *sub judice* in December 1986. He apparently had not expressed such an opinion previously to any of the other physicians who worked with the patient.

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[3] The court notes that Dr. Mahalak stated that in reviewing some 2,000 medical articles that he could not find any support for the claim that Accutane causes seizures.

Dr. William J. Riley, a neurologist of Houston, Texas, who never examined or treated the plaintiff, was permitted to testify by deposition as to his opinion regarding the cause of the plaintiff's 1984 neurological problems based on his review of the medical records. This deposition testimony was obtained before Mrs. Thomas suffered the 1989 seizure and he accordingly was not aware of the most recent episode. Dr. Riley testified that in his opinion the cause of the plaintiff's encephalopathy was her body's idiosyncratic or allergic reaction to the drug Accutane. Dr. Riley's testimony was based on his examination of the medical records from Dr. Dominic's Hospital in Jackson, the two admissions to the Mayo Clinic in Rochester, Minnesota and the records from the University of South Alabama Hospital in Mobile. The testimony of Dr. Riley failed to reveal any reliance or examination by him of medical literature relative to the pharmacology of Accutane and clearly he did not rely on any epidemiological study or data in reaching his opinion. The court notes that the testimony of Dr. Riley is similar to that which was excluded in the case of *Washington v. Armstrong World, Inc.*, 839 F.2d 1121 (5th Cir. 1988) where the purported expert did not have any contact with the patient.[4]

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[4] The defendant's expert, Dr. Chalhub likewise did not personally examine or treat the plaintiff and based his testimony on an examination of the hospital and medical records. However, the instant case differs from most pharmaceutical drug product liability cases in that many of the key witnesses for the defendant did treat the plaintiff during her numerous hospitalizations.

The Fifth Circuit Court of Appeals Recently decided the case of *Brock v. Merrell Dow Pharmaceuticals, Inc., supra.* The initial Brock decision held that conclusive epidemiological proof was essential to the plaintiff's case in a toxic tort pharmaceutical drug setting. The decision was subsequently modified and amended on August 15, 1989, after the trial of this case, to provide that a plaintiff in a prescription drug product liability case must present statistically significant epidemiological proof. *Brock,* 884 F.2d 166 (5th Cir.1989). The modification to the opinion contained the following language, to-wit:

> Hopefully our decision will have the effect of encouraging district judges faced with medical and epidemiological proof in subsequent toxic tort cases to be especially vigilant in scrutinizing the basis, reasoning, and statistical significance of studies present by both sides. However, we do not wish this case to stand as a bar to future benedictin cases in the event that new and statistically significant studies emerge which would give a jury a firmer basis on which to determine the issue of causation.

Brock, supra. The *Brock* court, *citing Richardson by Richardson v. Richardson-Merrell, Inc.,* 857 F.2d 823 (D.C.Cir.1988), reasons that without some epidemiological study or statistical basis for the expert's opinion that the opinion as to causation amounts to little more than speculation. *But see Brock,* 884 F.2d at 167 (denial of rehearing en banc) (dissents of Reavley, Politz, King, Johnson, Williams and Higginbotham, J.J. and separate dissent of Higginbotham, J.).

In the case *sub judice* given the discussion of the possible elimination of other causes and the possibility of

Accutane causing the plaintiff's 1984 seizures as testified to by Dr. Mahalak, this court finds that the rationale stated by the Fifth Circuit Court of Appeals in *Brock, supra* must be applied to the case *sub judice.* The court accordingly is of the opinion that the testimony of Drs. Mahalak and Riley amounts to speculation on their part as to what could have caused the 1984 seizures experienced by the plaintiff herein. The court notes that there is a total absence of any statistically significant study to assist the jury in its determination of the issue of causation. While many of the witnesses acknowledged an incidence of seizures in the general population, no witness, including the plaintiff's witnesses Drs. O'Donnell, Mahalak and Riley, offered any meaningful testimony connecting the ingestion of the drug Accutane with seizures from an epidemiological standpoint. In applying the logic of the *Brock* causation rationale to the facts in the case *sub judice,* the court must note that the highly qualified expert witnesses Causey, Chalhub, Kase, and Swanson all testified that the plaintiff's 1984 seizures were caused by some infectious or inflammatory process, not by ingestion of the drug Accutane. In taking into account the total absence of any epidemiological proof from the plaintiff, the court is of the opinion in applying *Brock* to the case *sub judice* that the motion for judgment notwithstanding the verdict should be granted.

WARNINGS

In this diversity action this *Erie*-bound federal district court looks to the substantive law of the State of Mississippi on the issue of the adequacy of warnings furnished

to the medical community by the defendant drug manufacturer, Hoffman-La Roche, Inc.[5] The plaintiff alleges that the defendant's negligent failure to furnish the prescribing physician adequate warnings as to the drug's propensity to cause seizures was a cause of the 1984 neurological episodes and seizures experienced by the plaintiff, Mrs. Thomas.

In this regard Mississippi adheres to the "learned intermediary" doctrine insofar as the sale and distribution of prescription drugs are concerned. This concept provides "that where prescription drugs are concerned, a manufacturer's duty to warn only extends to the physician and not to laymen." *Swayze v. McNeil Laboratories, Inc.*, 807 F.2d 464, 469, 470 (5th Cir.1987); *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.1974). The doctrine is firmly established in the jurisprudence of the State of Mississippi that if the warnings are adequate to the physician, then the manufacturer ordinarily is freed from liability. This legal premise, of course, is founded on the principal that the physician through education, experience, and specialized training is in the best position to make a benefit/risk analysis in making the determination to prescribe a particular drug for a specific patient. *See also Mauldin v. Upjohn Co.*, 697 F.2d 644 (5th Cir.), *cert. denied*, 464 U.S. 848, 104 S.Ct. 155, 78 L.Ed.2d 143 (1983); *Timm v. Upjohn Co.*, 624 F.2d 536 (5th Cir.1980), *cert. denied*, 449 U.S. 1112, 101 S.Ct. 921, 66 L.Ed.2d 840 (1981).

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[5] *Erie R.R. v. Tompkins*, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938).

In *Wyeth Laboratories, Inc. v. Fortenberry,* 530 So.2d 688, 691 (Miss.1988), the Mississippi Supreme Court held that proximate or legal cause must be proven. A plaintiff in a prescription drug products liability case has the burden of proving that an adequate warning to the prescribing physician would have altered the physician's conduct. The Mississippi Supreme Court in *Fortenberry, supra,* quoted the following language from *Kirsch v. Picher International, Inc.,* 753 F.2d 670, 672 (8th Cir.1985), to-wit:

> When viewed in a light most favorable to the plaintiff, there is simply no evidence that Dr. Murphy did not know of the danger in using radiation therapy. On the contrary the only evidence is that he had such knowledge. Any failure to warn by Picher would not have been the proximate cause of Kirsch's injuries.

The record reveals that Dr. Robert P. Myers of Columbus, Mississippi, a dermatologist, was the prescribing physician in the case *sub judice.* Dr. Myers testified that he had been treating the plaintiff for several years, that he diagnosed her skin condition as being nodulocystic acne and that she had been nonresponsive to the antibiotics Minocycline and Achromycin over a period of several years. Dr. Myers testified that he prescribed Accutane for Mrs. Thomas on or about January 24, 1984. Dr. Myers testified that he had participated with a Dr. Mitchell Sams in treating a teenager with severe cystic acne at the University of Alabama Hospital in Birmingham, Alabama with Accutane while the drug was in the premarket clinical trial stage. He testified that the drug had a remarkable result in treating this patient who had an advanced and serious acne condition. Dr. Myers further testified that in

the fall of 1983 he read a medical journal article by a Dr. Shalita and others wherein it was reported that rare idiopathic seizures had occurred during therapy using isotretinoin, a compound related to Accutane. He also testified that he was aware of reports of the occurrence of pseudo tumor cerebri occurring as an adverse reaction to the drug Accutane. Dr. Myers testified that at the time he prescribed Accutane for the plaintiff he had prescribed the drug for more than 500 patients, including his own son and daughter. Dr. Myers further testified that he deemed the Shalita article which he read in the fall of 1983 to be important in that he knew the dermatologists who wrote the article and he recalled discussing the article at the 1983 annual meeting of the American Academy of Dermatologists. The doctor further testified on his direct examination when questioned by the plaintiff's attorney that he was aware of the relationship between Accutane, Retinoids and Vitamin A. He was aware prior to January 1984 that seizures, unconsciousness and pseudo tumor cerebri had been reported in medical literature as being associated with high doses of Vitamin A. The prescribing physician testified that he had prescribed or administered the steroids Decadron and Aristocort to the plaintiff even though the Physicians' Desk Reference listed psuedo tumor cerebri, seizures and psychological changes as possible side effects of these steroids. Dr. Myers testified that before he prescribed a drug for any patient he relied upon his education and training, medical literature, discussions with colleagues, his prior clinical experience, the Physicians' Desk Reference, package inserts, and the patient's history in making a risk/benefit analysis. He stated that if in his professional opinion the

benefits of a drug outweighed the risk associated with it, that he would proceed with prescribing the drug for a specific patient. Dr. Myers testified that is precisely what he did in prescribing the drug Accutane for the plaintiff, Mary Kathryn Thomas. The following colloquy took place during the cross examination of Dr. Myers, to-wit:

> Q Dr. Myers, if the package insert available when you prescribed Accutane for Mrs. Thomas in January 1984 had said in the adverse reaction section that seizures had been reported in patients taking Accutane, would you still have prescribed the drug for Mrs. Thomas?
>
> A Yes, Sir.
>
> Q Would you please tell us why?
>
> A You have to weigh the benefit versus risk ratio. And I thought the benefit would certainly outweigh the risk. And I have an – I haven't ever seen anything that just strictly ties in Accutane equals seizures.

In looking to the plaintiff's evidence, the court is of the opinion that had the defendant Hoffman-La Roche, Inc. given the warning suggested by the plaintiff's witness Dr. O'Donnell, the conduct of the prescribing physician, Dr. Robert P. Myers, would not have been altered. The factual statements in the case *sub judice* by the prescribing physician are very similar to those in the cases of *Goodson v. Searle Laboratories*, 471 F.Supp. 546 (D.Conn.1978) and the Accutane case tried in the state court in Florida, *Felix v. Hoffman-La Roche, Inc.*, 513 So.2d 1319 (Fla.Dist.Ct.App.1987) and in the United States District Court for the Western District of Tennessee in *Dunkin*

v. Syntex Laboratories, Inc., 443 F.Supp. 121, 124 (W.D.Tenn.1977). In each of the foregoing cases, the trial court's grant of summary judgment was upheld on appeal when the affidavits and proof provided that the conduct of the prescribing physician would not have been changed had a different or more adequate warning been given. The Florida appellate court in an Accutane law suit stated as follows, to-wit:

> The prescribing physician testified not only that he understood the warnings but that he had prior knowledge of [the side effects alleged] from independent research and reading and from seminars he had attended. . . . [It is] clear . . . that at the time he prescribed Accutane, he was aware of the dangers. . . . Consequently, the undisputed evidence demonstrates that any inadequacy in the warning provided was not the proximate cause of [plaintiff's] damages and that the defendants were, therefore, entitled to judgment as a matter of law.

Felix, supra 1321 (Fla.Dist.Ct.App.1987).

In her post trial brief, the plaintiff argues that the case of *Hermes v. Pfizer, Inc.*, 848 F.2d 66 (5th Cir.1988), where the plaintiff recovered in a pharmaceutical products liability case applying Mississippi substantive law, sets forth controlling principals that should be applied in the case *sub judice*. *Hermes* involved the drug Sinequan and it was held that the manufacturer Pfizer did not furnish the medical community adequate warnings of the possible side effect "extrapyramidal" symptoms or "hunting jaw." In *Hermes*, an oral surgeon, Dr. Metts, testified that he had prescribed Sinequan for his mother and that when she experienced "hunting jaw" symptoms similar

to those experienced by Mrs. Hermes, he took her off of the medication. Further, the reported decision in *Hermes* does not reflect that the prescribing physician, a gynecologist, Dr. Bourgeois, testified as did Dr. Myers in the case *sub judice* that he was familiar with the drug, had prescribed it for hundreds of patients, and would have prescribed it even if the suggested warnings had been given by the manufacturer of the drug. Also, it is noteworthy that the defendant in *Hermes* apparently did not raise an issue relative to the absence of epidemiological proof in that case.

The plaintiff also points out that *Brock, supra,* is a Benedictin case and that numerous epidemiologic studies have been conducted relative to that specific drug. This court notes that the *Brock* court cites and discusses cases involving the swine flu vaccine, urea-formaldehyde, paraquat and Agent Orange. This court is of the opinion that *Brock, supra,* is applicable to and controlling in the case before this court.

The court has carefully reviewed the evidence with all favorable inferences in the light most favorable to the plaintiff. The court holds that pursuant to the rationale of the Fifth Circuit in *Brock v. Merrell Dow Pharmaceutical, Inc., supra,* and the pronouncement of the Mississippi Supreme Court in the case of *Wyeth Laboratories v. Fortenberry, supra,* the motion for judgment notwithstanding the verdict is well taken. In so ruling, the court notes a complete absence of any epidemiological proof associating the drug Accutane with seizures and a total failure of the plaintiff to adduce evidence that Dr. Myers would not have prescribed Accutane if the defendant had furnished the suggested warnings. A separate order will issue accordingly.